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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,712	05/04/2001	Nobutaka Wakamiya	19036/37157	9190

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,712	WAKAMIYA, NOBUTAKA	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97-155* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97-155* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/27/03, 2/19/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is a reply to the Amendment and Response of 3 November 2003 filed in response to the Non-Final Office Action mailed 29 April 2003. Claims 82-92, 95 and 96 were withdrawn from consideration and claims 38-81, 93 and 94 were considered in the 29 April Office Action. Claims 38-96 were canceled and claims 97-155 were added in the 3 November Paper. Claims 97-155 are pending and under consideration.

Response to Amendment

Rejection of claims 38-81, 93 and 94 is rendered moot by cancellation of the claims.

Double Patenting

Applicant is advised that should claims 107 and 108 be found allowable, claims 102 and 103 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 107 and 108 are exact duplicates of claims 102 and 103, respectively. It is assumed that this is an inadvertent typographical error and, in the interest of expediting prosecution of the application, it is assumed that the polypeptide of claim 107 should consist of from the 206th to the 547th amino acid of SEQ ID NO: 2 and the polynucleotide of claim 108 should hybridize to a polynucleotide complementary to nucleotides 670-1695 of SEQ ID NO: 1.

Specification

Objection to the specification as lacking a descriptive title is withdrawn in view of the amendment to the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 97-155 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The reasoning for this rejection is the same as the reasoning set forth in the previous Office Action in rejecting claims 38-81, 93 and 94 under 35 U.S.C. 101.

Response to Arguments

In response to the rejection of record, Applicant alleges that the premise of the rejection is unsound because one of skill in the art is aware that substantial differences in primary structure exist between members of the collectin family of proteins, and yet the family members share a common function of increasing immunity against various microorganisms. Applicant urges that the 35% identity between SP-D and the disclosed polypeptide is comparable to the homology found within the collectin family and that the presence of certain motifs found in other collectins adequately demonstrates that the claimed protein is a member of the collectin family, and has the function of a collectin. Applicant argues that collectins such as conglutinin and mannan-binding

protein inhibit infection and hemaglutination activity of Influenza viruses and therefore, "the claimed collectin polynucleotide and polypeptide in the instant application have demonstrated credible, specific and substantial utility because the collectins can be used in a variety of real world contexts to combat a number of infectious diseases".

These arguments have been fully considered but are not deemed persuasive. Importantly, Applicant states, "[c]ollectins do not have higher order structural features, such as the transmembrane region, leucine-zipper region, region b, and α-coiled region which differentiate them structurally and functionally from the scavenger receptor proteins cited by the Patent Office. In addition, scavenger receptor proteins cannot take on an oligomeric form characteristic of collectins" (page 14, paragraph 2). Thus, Applicant appears to acknowledge the skilled artisan would not expect that a scavenger receptor, or a portion thereof, would have the functions ascribed to collectins.

As described in the previous Office Action (page 6, first full paragraph), art published two years after the instant application was filed clearly establishes that the claimed polypeptide is, in fact, a fragment of a scavenger receptor. Specifically, Figure 1 of Nakamura *et al.* (2001) *Biochem. Biophys. Res. Commun.* 280:1028-1035 discloses a nucleic acid sequence that comprises all but the 3' most 4 nucleotides of the instant SEQ ID NO: 1 (compare nucleotides 532-2550 to nucleotides 1-2019 of the instant SEQ ID NO: 1). Thus, the instant SEQ ID NO: 1 is clearly a fragment of the sequence disclosed by Nakamura *et al.* Furthermore, the C-terminal portion, beginning at amino acid 401, of the polypeptide encoded by the nucleic acid sequence of Nakamura *et al.* comprises the entirety of SEQ ID NO: 2. Nakamura *et al.* also teaches that the polypeptide encoded by the nucleic acid comprises an additional 400 amino acid N-terminal

portion which identifies the polypeptide as a scavenger receptor. This is acknowledged in Applicant's own publication (Ohtani *et al.* (2001) *J. Biol. Chem.* 276:44222-44228; also made of record in the previous Office Action). All of the teachings in the instant specification regarding the utility of the claimed protein and nucleic acid are predicated on its being a soluble collectin. However, the post filing art, including Applicant's own work, clearly demonstrates that the claimed invention is, in fact, a portion of a scavenger receptor and, to the extent that the claims embrace any polypeptide comprising the fragment, the scavenger receptor itself. Based on the teachings of the specification and general knowledge in the art at the time of filing the skilled artisan could not possibly have known how to use the claimed invention because the true nature of the invention was unknown.

A patentable utility under 35 U.S.C. §101 must be *specific* to the subject matter claimed. In the instant case the utilities asserted are based on the assumption that the invention is a soluble collectin, which is demonstrated to be a false assumption years after the application was filed. At the time of filing there was no evidence, and to this day there is no evidence to support applicant's assertion that the fragment of a scavenger receptor disclosed in the instant application can be used to combat a number of infectious diseases; and given Applicant's own admission that scavenger proteins are functionally different from collectins, the skilled artisan would not immediately recognize that a fragment of a scavenger receptor would have the function of a collectin.

Applicant's arguments are not deemed persuasive either individually or as a whole. Therefore, the newly filed claims are rejected under 35 U.S.C. §101. Applicant should explicitly identify a specific and substantial credible utility for the claimed invention and establish a

probative relation between any evidence of record *and the originally disclosed properties* of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 97-155 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 145-152 and 155 are additionally rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 155 is directed to a mouse comprising a polynucleotide encoding a polypeptide having an amino acid sequence that comprises positions 229-547 of SEQ ID NO:2. Claims 145-152 are directed to a host cell expressing various fragments of the polypeptide set forth as SEQ ID NO: 2. As the host cells are not limited to being isolated or *in vitro*, the claims read on the cell comprised within the transgenic animal contemplated in the specification.

In the previous Office Action, beginning in the fourth paragraph on page 8, a *prima facie* case of non-enablement was set forth regarding claims directed to transgenic animals. The Office Action states, "[t]he teachings [provided in the disclosure] do not provide a single phenotypic characteristic of the claimed animal such that the skilled artisan would know how to use the animal" and concludes, "[a]lthough the relative level of skill in the art is high, given the art-recognized unpredictability of the phenotype arising from disruption of any given gene in any given animal, the skilled artisan would have to resort to trial and error experimentation in order to uncover a useful phenotype in the claimed animal. As there is no routine method with which the skilled artisan can identify or predict the phenotype arising from genetic manipulation of an animal, the level of experimentation required to use the claimed invention would clearly be undue" (page 10).

Response to Arguments

In response to the rejection of record Applicant argues that claims directed to a transgenic mouse are enabled because "it is well within the skill of artisans practiced in this field to prepare the transgenic mice of the present invention as a mater of routine practice and to use such mice in screening of the claimed invention" (paragraph bridging pages 15-16).

This argument has been fully considered but is not deemed persuasive. The first paragraph of 35 U.S.C. §112 requires that the written description set forth the process of using the invention in full, clear, concise, and exact terms. The teachings of the specification provide protocols for making a transgenic mouse, which are well known in the art, and a general statement that the mice produced by the method can be used in screening. However, given the art

recognized unpredictability of phenotype established in the previous Office Action, the skilled artisan would have no idea what the screening process relied upon to satisfy the "how to use" requirement would entail. How can the skilled artisan know what to measure if the novel aspects of the claimed invention are unknown? How is the skilled artisan to use the products of the screening process if there is no disclosure of what properties of those products are identified by the screening process? The teachings of the specification regarding how to use any animal, including a mouse or cell comprised within a transgenic mouse are far from full, clear, concise, and exact. Therefore, the disclosure fails to adequately enable the claimed products.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims are rejected under 35 U.S.C. §112, first paragraph, as lacking enablement.

Claims 98, 99, 101, 103, 104, 106, 108, 109, 111, 113, 114, 116, 118, 119, 121, 123, 124, 126, 128, 129, 131, 133, 134 and 136-155 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 98, 99, 101, 103, 104, 106, 108, 109, 111, 113, 114, 116, 118, 119, 121, 123, 124, 126, 128, 129, 131, 133, 134 and 136 are directed to isolated polypeptides and polynucleotides, wherein the claimed polypeptide encompasses any polypeptide encoded by a polynucleotide that hybridizes to a polynucleotide complementary to a fragment of the nucleic acid sequence set

forth as SEQ ID NO: 1 or comprises a fragment of SEQ ID NO: 2 wherein one or more amino acids are deleted substituted or added, or wherein the polynucleotide comprises a nucleotide sequence that hybridizes to a polynucleotide complementary to a fragment of the nucleic acid sequence set forth as SEQ ID NO: 1. Claims 137-155 are directed to vectors, host cells, probes and a transgenic mouse comprising the polynucleotides. The previous Office Action establishes a *prima facie* case that the instant disclosure fails to adequately describe nucleic acids and polypeptides beyond the scope of those polypeptide and nucleic acid sequences explicitly set forth in the disclosure (beginning at the third full paragraph on page 10).

Response to Arguments

Applicant asserts that the newly presented claims are adequately described.

First, Applicant alleges that new independent claims 98, 101, 103, 106, 108, 111, 113, 116, 118, 121, 123, 126, 128, 131, 133, and 136 are directed to an isolated human collectin polypeptide consisting of particular regions in the amino acid sequence of SEQ ID NO:2; which may include one or more amino acid(s) deletions, substitutions and/or additions as long as it is encoded by a polynucleotide which hybridizes under particular hybridization conditions (paragraph bridging pages 16-17). However, this is a mischaracterization, as claims 98, 101, 103, 106, 108, 111, 113, 116, 118, 121, 123, 126, 128, 131, 133, and 136 are not at all limited to "consisting of particular regions of the amino acid sequence of SEQ ID NO: 2". The claims reciting hybridization conditions embrace any polynucleotide that hybridizes to the portions complementary to SEQ ID NO: 1 set forth in the claims, and polypeptide encoded thereby. Thus, the claims encompass any polynucleotide comprising the hybridizing sequence and any

polypeptide encoded thereby. With regard to the claims directed to polypeptides wherein amino acids are deleted, substituted or added, the scope of the claimed polypeptide clearly goes beyond that of "consisting of particular regions in the amino acid sequence of SEQ ID NO:2".

Applicant cites Example 9 of the written description guidelines and argues that the instant claimed nucleic acids and polypeptides are similarly described by the hybridization conditions set forth in the claims. In the paragraph bridging pages 17-18, Applicant cites teachings in the examples indicating that the claimed polynucleotide can be obtained using the hybridization conditions recited in the claims and notes that Applicant has succeeded in isolating a polynucleotide which hybridizes to probes disclosed in the examples.

These arguments have been fully considered but are not deemed persuasive. The facts set forth in Example 9 of the written description guidelines are clearly different from those of the instant case. First, the Example is specifically directed to claims to a nucleic acid, not to a protein encoded by a nucleic acid or to any mutant thereof comprising one or more amino acid deletions, substitutions or additions. The Example stops well short of indicating that the disclosure of a nucleic acid sequence and a method of hybridization adequately describes any protein, or mutant thereof, that is encoded by a hybridizing nucleic acid. Furthermore, the example clearly states that the specification includes an example wherein several hybridizing nucleic acids were expressed and shown to have the activity explicitly set forth in the claim. In the instant case, the Examples disclose a single nucleic acid obtained by hybridization and provides no evidence that the polypeptide encoded thereby has the activity asserted in the specification. Clearly the instant disclosure falls well short of the disclosure provided in Example 9, and the instant claims are of

much broader scope than the claim analyzed in Example 9. Therefore, the cited Example does not support Applicant's position.

Thus, for reasons set forth in the previous Office Action and herein, the disclosure fails to provide adequate descriptive support for nucleic acids and polypeptides beyond the scope of those polypeptide and nucleic acid sequences explicitly set forth in the disclosure

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 137-154 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 137-144 are indefinite because there is no antecedent basis for the polynucleotide of the claims. The claims are directed to a vector comprising a polynucleotide set forth in a preceding claim, while all of the claims from which they depend recite only polypeptides. It is assumed that this is an inadvertent typographical error and, in the interest of expediting prosecution of the application, it is assumed that claim 137 should depend from 100, 138 should depend from 105, 139 should depend from 110, 140 should depend from 115, 141 should depend from 120, 142 should depend from 125, 143 should depend from 130 and 144 should depend from 135.

Claims 145-152 are indefinite insofar as they depend from claims 137-144, respectively.

Claim 153 is indefinite in being directed to a probe consisting of the polynucleotide according to claim 98. There are two polynucleotides in claim 98; one which is complementary to nucleotides 730-1695 of SEQ ID NO: 1, and one which hybridizes to the polynucleotide complementary to nucleotides 730-1695 of SEQ ID NO: 1.

Claim 154 is indefinite insofar as it depends from claim 153.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 98, 99, 101; 103, 104, 106, 108, 109, 111, 113, 114, 116, 118, 119, 121, 123, 124, 126, 128, 129, 131, 133, 134 and 136-154 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/55614 (published 10 December 1998; made of record in the IDS filed 19 February 2003; hereinafter '614).

In the previous Office Action, the '614 application was mistakenly identified as WO 98/55617. This was an obvious typographical error as the Office Action clearly states that the WIPO document referred to was made of record by Applicant in the IDS filed 19 February 2003. There were two WIPO documents made of record in that IDS, one of which was WO 98/55614 and neither of which was 98/55617. In spite of this, Applicant feels it is not clear what sequence the Patent Office is referring to in the rejection. Therefore, the rejection will be applied to the presently pending claims and this Office Action is made non-final to allow Applicant an

opportunity to respond to the rejection. In the interest of expediting prosecution of the application, Applicant is urged to familiarize himself with the prosecution history of the present application.

The sequence set forth in '614 as SEQ ID NO: 11 fully comprises 1-2019 of the instant SEQ ID NO: 1 and thus anticipates the polynucleotide claimed in claims 101, 106, 111, 116, 121, 126, 131, 136 and 154 and encodes the polypeptide of claims 98, 99, 103, 104, 108, 109, 113, 114, 118, 119, 123, 124, 128, 129, 133 and 134. Beginning the third paragraph on page 42 and continued through the second paragraph on page 43, '614 teaches vectors and host cells comprising the nucleic acid comprising SEQ ID NO: 11 according to the limitations of claims 137-152 and on page 45, paragraph 2, '614 teaches a probe comprising a fragment of the polynucleotide comprising SEQ ID NO: 11 according to claim 153. The polynucleotide, vector, host cell, probe and method taught in '614 are the same as those taught in the instant application; therefore, the limitations of the claims are met by '614.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP §201.15.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER